

PSJ10 Exh 64



**US Order Management**  
**Master Data / License Admin. Operational Procedure**

|                                     |   |                |              |
|-------------------------------------|---|----------------|--------------|
| PROCEDURE:                          | License Maintenance<br>Create, Change License or Create, Change Listing/Exclusion for<br>Controlled and Non-Controlled substance License  |                |              |
| USOM POLICY #:                      | USOM-LIC-4000   | Effective Date | May 3, 2004  |
| Revision written by:                | Victoria Lepore<br>Mary Moskello  | Revision date: | June 5, 2014 |
| USOM CTMAN Document #               | CTMAN 080-045   |                |              |
| CTM Transaction:                    | VX01N- License Create<br>VX02N- License Change<br>VB01- Create Listing / Exclusion<br>VB02- Change Listing / Exclusion<br>VE30- Existing Licenses<br>VE31- License Blocked Sales Orders<br>VCH1- Create Batch Search Strategy<br>VCH2- Change Batch Search Strategy |                |              |
| Prerequisites SAP Transaction Code  | VD01- Create Customer<br>VD02- Change Customer  |                |              |
| Post réquisits SAP Transaction Code |   |                |              |

TABLE OF CONTENTS

|   |    |
|---|----|
| Scope .....                                 | 1  |
| Procedure.....                              | 1  |
| A. DRUG SUBSTANCES – Controlled:.....       | 2  |
| 1. DEA License .....                        | 2  |
| 2. Creating Exclusion Record.....           | 3  |
| 3. Violations .....                         | 3  |
| 4. NTIS Disc.....                           | 3  |
| 5. Licensing Issues .....                   | 6  |
| 6. TIRF REMS Registration .....             | 6  |
| 7. Health Identification Number (HIN).....  | 7  |
| 8. License blocks.....                      | 7  |
| 9. CII Schedule Drugs and SOMS blocks ..... | 7  |
| B. Filing: Record Retention: .....          | 9  |
| C. License for One Time Customer: .....     | 9  |
| D. Unlicensed Locations:.....               | 9  |
| E. Methamphetamine Control Act: .....       | 9  |
| F. Indigent Accounts:.....                  | 10 |
| G. PapSure Physician Address Changes:.....  | 10 |
| H. R&D Research and Development: .....      | 10 |

Purpose

Establish and maintain the proper method of applying licensing information on an account to ensure compliance with the Drug Enforcement Administration (DEA) licensing requirements and the Prescription Drug Marketing Act (PDMA), as well as, the National Association of Boards of Pharmacy.

Scope

All Call Center Operations employees directly or indirectly responsible for customer account maintenance

Procedure

Once a customer account has been opened, updated, or unblocked, the Master Data Administrator (MDA) will review and verify the licensing information for accuracy.

All information necessary for analysis, review and validation of a license must be submitted to the SAP Master Data Administrator (MDA).

The following information is verified against the current License for accuracy:

- 1. Customer Name
- 2. Ship-To Address

Note: Ship-to address MUST match the DEA License. However PDMA regulations policy to ship non-controlled sample products only to a facility that the requesting practitioner operates from. If the address of the licensed



Actavis Pharma Inc.

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| Page 2 of 12         |  |                 |              |

practitioner does not match the address of the practitioner’s license, then the MDA and/or CRA/SAA must verify that the practitioner does practice at the Ship-to address. Verification of the practitioner address may be done by obtaining a copy of the doctor’s valid state license, a phone call to the facility, finding the location on the internet via the yellow pages or comparable search engine, or avoided Rx that shows the practitioner at the Ship-to.

- 3. DEA number / State License
- 4. DEA expiration date / State License expiration date
- 5. Approved Drug Schedule(s)
- 6. It is mandatory that a State license be created on all RX including Florida accounts. Due to the State of Florida Pedigree requirements, it is mandatory that the FL DOH Permit # (State License) appears on all packing list and must be submitted to open a new account.
- 7. It is important that the State license is NOT expired or else it will not appear on the packing list.

The system is set to capture legal blocks on Florida accounts missing a State license. There are three scenarios for legal blocks for the State of Florida:

- State legal block during order processing if the ship-to license is missing.
- State legal block during order processing if the ship-to license has expired.
- State legal block during order processing if the ship-to license expires within 7 day ship window.
- There is a SAP Prerequisite requirement that is maintain by IT which is called ZGLOBAL\_PARAM table. If another State needs to be added for Epedigree requirements, the MDA will send an email to the IT team to add a State to the ZGLOBAL\_PARAM table.

Please take note: Accounts are not deleted or de-activated. When an account is no longer in use, i.e. per customer request, location has moved, or any other reasons, the MDA will block the account and expire all current licenses attached to the account. Also the MDA will report to the Board of Pharmacy, FDA and DEA in 3 business days if unable to authenticate the vendor/customer.

**A. DRUG SUBSTANCES – Controlled:**

**1. DEA License**

DEA license is required for orders containing controlled substances. The DEA license includes the DEA license number, DEA license expiration date and the approved drug schedules (2, 2N, 3, 3N, 4, 5).

| Schedule | Regulatory Definitions  |
|----------|---|
| 2        | High Potential for abuse. Use may lead to severe physical or psychological dependence. No renewals are permitted  |
| 2N       | Same as above except, Non-narcotic  |
| 3        | Some potential for abuse. Use may lead to low to moderate physical dependence or high psychological dependence. Up to 5 renewals are allowed within 6 months. |
| 3N       | Same as above except, Non-narcotic  |
| 4        | Low potential for abuse. Use may lead to limited dependence either physically or psychologically. Up to 5 renewals are permitted within 6 months.             |
| 5        | Subject to state and local regulation. Abuse potential is low; a prescription may not be required.  |
| Rx       | Prescription (SAP requirement)  |

Verification of the DEA license number, DEA shipping address, and DEA expiration date and drug schedule can be made by:

- a. Using The U.S. Department of Commerce National Technical Information Services (NTIS) Drug Enforcement Administration (DEA) website: <http://deanumber.com/> (See Exhibit A).
- b. Obtaining a photocopy of the DEA license certificate from the customer.

If the copy received from the customer is not legible and does not exist on the DEA website (NTIS) or the DEA license has expired, the MDA will leave the order on license block in SAP, until the appropriate documentation is received. The MDA will contact the customer or the CRA responsible for the account to request a valid/current photocopy of the DEA License. The MDA will update the account upon receipt of a valid DEA license to remove the block on the order in SAP. The MDA will also communicate and report back to the Customer Support department on the licensing status, if necessary.

If the photocopy of the DEA License is not received, the MDA will contact the customer or the CRA responsible for the account a second time requesting the photocopy of the DEA license. If the photocopy of the DEA license is not received, the customer will be notified that the pending order will be cancelled until a valid DEA license is received. The MDA will update the account with an overall block until a valid license has been received. Once a valid license has been received the overall block will be removed.

\*NOTE: Only the schedules (2, 2N, 3, 3N, 4, 5) that are registered and shown on the license will be created in SAP. Also, customers with a DEA license automatically receive schedule Rx.

Retail Outlets and Practitioners must register all schedules to receive shipment.

The check digit algorithm will determine the validity of a DEA number. The seventh digit of the DEA number is the Check Digit. Add the first, third, and fifth digits to equal SUM1. Add the second, fourth, and sixth digits and then multiply by 2 for Sum2. Add SUM1 + SUM2. The last digit of this



Actavis Pharma Inc.

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| Page 3 of 12         |  |                 |              |

total should equal the seventh (Check Digit) of the DEA #.

Note: On occasion DEA licenses with only 1 letter at the beginning (i.e. R10184159) may be submitted. These licenses are usually submitted by customers that have a name that starts with a number (i.e. 212 Pharmacy). The check digit algorithm can still be used by treating the first number as the 2<sup>nd</sup> letter of a typical DEA license. If necessary, the DEA can be called directly to verify the validity of a license.

| DEA check digit algorithm          |       |        |       |        |       |       |                       |             |      |
|------------------------------------|-------|--------|-------|--------|-------|-------|-----------------------|-------------|------|
| For example: DEA License RW0184159 |       |        |       |        |       |       |                       |             |      |
| DEA                                | First | Second | Third | Fourth | Fifth | Sixth | Seventh (check digit) | Results     |      |
| RW                                 | 0     |        | 8     |        | 1     |       | 9                     | 9           | Sum1 |
|                                    |       | 1      |       | 4      |       | 5     |                       | 10 x 2 = 20 | Sum2 |

2. Creating Exclusion Record

Three exclusion methods are currently being used, Customer/Schedule Number, SalesDocType/Ord.reason/Sch No., and Customer/Material. The Customer/Schedule Number exclusion is set up is when the customer requests to exclude schedules. The customer may request to exclude schedules because the facility does not have proper storage and/or when the customer does not wish to receive those schedules. The SalesDocType/Ord.reason/Sch No. is setup when it is decided that a specific Order Type (i.e. Standard Order) and Order Reason (i.e. Drop ship) should not receive certain schedules. The Customer/Material is used the when specific materials will not be ordered/shipped to a specific customer.

When the customer is being investigated as directed from management, you need to expire the DEA license and exclude the customer’s schedules on 2, 2n, 3, 3n, 4 and 5 and create a State license for that customer.

No DEA license is added to any Ship-to unless the Sold-to and Ship-to account included in the request have been vetted and approved by DEA Affairs. All vetting documentation will be maintained by DEA Affairs and applicable approval will be noted on the new account form. Additionally any additional approvals will be noted on the new account form by all appropriate parties prior to the first “ship to” having a DEA license added.

If vetting is not approved, please add internal notes (to include DEA Affairs justification) to the ship to account and exclude all schedules 2, 2n, 3, 3n, 4 and 5 to prevent any orders being processed.

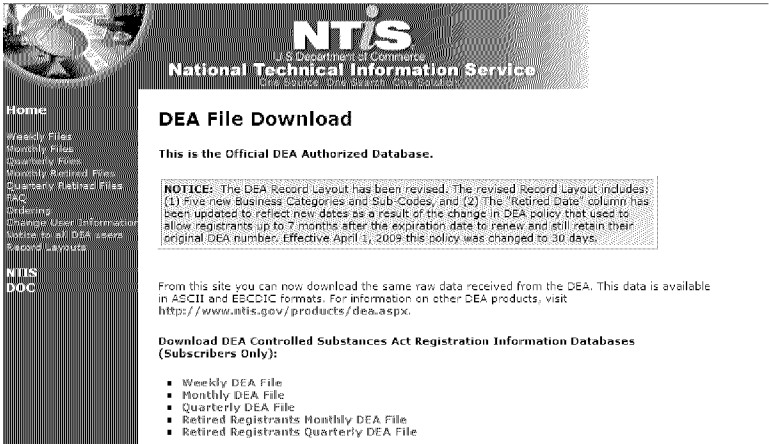
3. Violations

The Master Data Administrator (MDA) will review and release sales orders pending licensing verification. This is critical in order to remain in compliance with the DEA, State and PDMA law as it pertains to the sales and distribution of pharmaceutical products.

4. NTIS Disc

The Master Data Administrator (MDA) will download the NTIS file from the NTIS website on the first business day of the month; Go to [www.DEA.NTIS.GOV](http://www.DEA.NTIS.GOV)

The link and the password for the following website will be on the portal  
Go to [www.DEA.NTIS.GOV](http://www.DEA.NTIS.GOV)  
The screen will look as below:



Go to the “monthly file” link either to the left column or the bottom.



Actavis Pharma Inc.

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Page 4 of 12

Home

Weekly Files

Monthly Files

Quarterly Files

Monthly Retired Files

Quarterly Retired Files

FAQ

Ordering

Change User Information

Notice to all DEA users

Record Layouts

NTIS DOC

NTIS

U.S. Department of Commerce

National Technical Information Service

One Source. One Search. One Solution.

DEA Monthly File

The following files are available for the current and previous months. Note that both the ASCII and EBCDIC versions are available.

For your convenience, MD5 checksums for each file are listed below. These may be used to verify that you have successfully completed your download. In order to verify these checksums, you will need to obtain an MD5 sum generator. For your convenience, one is available through the Frequently Asked Questions (FAQs) page. If the MD5 sum generated by the program does not match the one for the corresponding file below, please retry your download.

The files are now available in zipped format:

ASCII Formatted Versions

| File Name | Size     | Date (Y/M/D) | Frequency | Record Count | MD5 Checksum                      |
|-----------|----------|--------------|-----------|--------------|-----------------------------------|
| MA11011   | 321.8 MB | 2011/11/07   | Monthly   | 1417660      | dd0217a130d242667fc286bcd68292bd0 |
| MA11010   | 320.8 MB | 2011/10/03   | Monthly   | 1413515      | 0e4ab69d5212444172f47e95bd6e61da  |
| MA11009   | 320.1 MB | 2011/09/05   | Monthly   | 1410453      | e3a1a0120a502bf3d203bfdec5cc721a  |
| MA11008   | 318.5 MB | 2011/08/01   | Monthly   | 1403141      | 3b19649bd5d5b2d237f41183792ff70a  |

Click on the zipped format link.

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Quarterly Files

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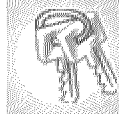
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ASCII Formatted Versions

| File Name   | Size    | Date (Y/M/D) | Frequency | Record Count | MD5 Checksum                     |
|-------------|---------|--------------|-----------|--------------|----------------------------------|
| MA11011.zip | 63.6 MB | 2011/11/07   | Monthly   | 1417660      | e5d937bb1071ec3157e3d49f712bab73 |
| MA11010.zip | 63.4 MB | 2011/10/03   | Monthly   | 1413515      | 1209c708f9ed7759eaf14ed6f74a776f |
| MA11009.zip | 63.2 MB | 2011/09/05   | Monthly   | 1410453      | a017f9476d493d7c73717f99aa9cf2ac |
| MA11008.zip | 62.8 MB | 2011/08/01   | Monthly   | 1403141      | 98953baace47643f9ba98eb5aaa7f89d |

Click once on the first file that starts with MA and ends with .zip  
This brings up as sign on screen:

Connect to dea.ntis.gov



The server dea.ntis.gov at DEA Monthly Access requires a username and password.

User name:

Password:

☐ Remember my password

OK

Cancel

Enter the following information:  
Username: 525246  
Password: Watson! 2011  
Checking the remember password is optional  
Click OK

Save file anywhere, usually desktop  
Go to the location where you saved it (usually desktop)  
Right click on the file and click on extracting all, Click Next  
Click OK (the default location is the desktop)  
Click Finish  
Now open the Customer Master folder and then the sub-folder NTIS File





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| Revision Written By: | Victoria Lepore<br>Mary Moskello   | Revision Date:  | June 5, 2014 |

Page 5 of 12

- Customer Master
  - 1 Pending (Initial request)
  - 3 Pending (Accounting)
  - 4 Pending (Contracts)
  - 5 Pending (License)
  - 6 Pending (Notify requestor)
  - Accounting Completed 2004
  - CARS Tools
  - Compensation
  - Completed
  - CUSTLISTS
  - Drive Shortcuts
  - Licensing Department
  - MEMBERSHIP
  - MISC
  - NTIS File

Click on the location where you stored the recent NTIS file (usually desktop) and drag the file to the NTIS File folder.

Copy the path for this location as below:  
V:\Sales Operations & Distribution\Customer Master\NTIS File

Send an email to the IT Dept along with the record count (found on the screen when you clicked on the “Monthly Files” on the original website). Make the subject of the email “NTIS File”.

Once the file is loaded into SAP by the IT Dept., an email will be sent to #Master Data on the updated DEA License using downloaded file from NTIS File folder.

\*NOTE: On a monthly basis, the DEA registration file information is loaded, by the Information Systems group. The updated information is in accordance with information on file at the DEA. This is inclusive of DEA license expiration date and authorized schedules. However, the DEA registration file information may not be as current as the DEA website mentioned above. The most current data should be used. Please see the Information Systems group update process below:

**Monthly DEA License Update from NTIS File Folder Process**

- Prod Support executes a trial run in a test system** – this is not done to update the license values in the test system, rather to determine whether there are any format or data problems with the CD. In the past 14 months we have had circumstances in which a) dates on the CD were incorrectly formatted and b) schedule values on the CD were not valid (licenses with Schedule 1). It is important to discover these errors and request a replacement CD from NTIS prior to using the CD to update the production system.
- Prod Support executes the custom License Update program in the production system** – a brief summary of the functionality of the program:

**Custom Program Name:** ZVI\_DEA\_LICENSE  
**Transaction Code:** ZVLICUPD

The program selects all active DEA license records from the SAP system. Each record is then matched against the uploaded NTIS file using DEA number, if found, the end dates and schedules of the SAP license and the NTIS entry are compared. If they are identical, no updates are made in SAP. If they are different (i.e., new end date, different schedules), the existing SAP license is expired and a new license is created using the values from the NTIS entry. If a match is not found, the SAP license is expired, as the validity of the license could not be confirmed with the NTIS file.

The program also dumps the full content of the NTIS file into a custom SAP table ZVDEA for reference purposes. After completion of the job, the number of records in this table is compared to documentation received with the file to confirm that the record counts match. This is done via transaction code ZVDEA.

If errors occur during the execution of the job, Prod Support will analyze and correct the errors. The job is usually executed the day the information is available, so that errors can be resolved with limited impact to the business.

- Post Processing Reporting** – after processing is complete, Prod Support produces a listing of expired and new licenses, using the SQVI Quick viewer query tool in SAP. The listing shows all licenses expired; and, if a new license was created (in the case of updates). This listing is sent to the Master Data Team for review.

**Notes:** One issue regarding this process is that a time lag will always potentially exist between receipt/application of the NTIS File and the actual status of the DEA licenses. The Licensing team has access to daily updated information on DEA licenses via the internet, including newly created licenses; they will capture and create/update licenses in the SAP system based on business requirements. However, as noted in the processing summary, if the NTIS File does not contain a license (i.e., perhaps a license just created/approved in the past week, after the latest NTIS File is loaded into the folder), the program will consider it invalid.

The Post Processing listing also contains information about the Created On date and Created by ID of a license. One possibility is for the Master Data Team to review the list by the Created on date, so that expired licenses that were created most recently will be readily apparent. These are the most likely to have been created/updated after the NTIS File was issued, and the Master Data Team can manually update them before any business impact is realized. If the license continues to be missing from the NTIS File month after month (requiring manual re-creation), this should be researched; supposedly, if it’s not on the file it doesn’t exist.



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| Page 6 of 12         |  |                 |              |

Licenses used on specific orders: this is not related to the update process in any way; however, this data is available via standard SAP transaction ENGK, using the Assigned Documents option under Alert Reporting. Among the search criteria available are license type, license number (internal SAP or external/DEA number), and Sold-to customer and schedule number.

**5. Licensing Issues**

Whenever there is a discrepancy between the information on the licensing website and the account, for example, the customer has recently moved to another address, but the website still reflects the old address. The Customer Relations Administrator should then contact the customer to verify the correct information and obtain the supporting documents. If the account needs to be changed, the CRA/ Specialty Account Administrator will need to fill out the appropriate form and submit according to standard procedures. If the Master Data group cannot update the address on the account within 48 hrs, then the Master Data group should EXPIRE the current license. Once the Master Data group has followed the procedure to correct the address in SAP then validate and re-instate the license according to standard procedures. If the customer has a new license number, then the current license should be expired immediately and a new license should be created according to standard procedures.

Validating Medical Prescriber’s State Licenses

The Master Data Administrator will validate the State License using the MEDPRO website.

In the event MEDPRO is not up to date, the Master Data Administrator visits the respective state website. If the MEDPRO and state website reflect an expired license, MDA will notify the CRA/SAA. The CRS/SAA will need to contact the customer to provide an updated license.

**6. TIRF REMS Registration**

The goals of the TIRF REMS Access Program are to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- Prescribing and dispensing TIRF medicines only to appropriate patients, which includes use only in opioid-tolerant patients.
- Preventing inappropriate conversion between fentanyl products.
- Preventing accidental exposure to children and others for whom it was not prescribed.
- Educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose of TIRF medicines.

Effective March 12, 2012, Sold-to (corporate locations) making a direct purchase from the manufacturer are required to have a distributor registration in order to purchase and receive the following Fentanyl Citrate EQ Oral Trans sku’s.

|             |  |
|-------------|--|
| 55253007430 | FENTANYL CITRATE EQ ORAL TRANS 1200MCG30 |
| 55253007530 | FENTANYL CITRATE EQ ORAL TRANS 1600MCG30 |
| 55253007030 | FENTANYL CITRATE EQ ORAL TRANS 200MCG 30 |
| 55253007130 | FENTANYL CITRATE EQ ORAL TRANS 400MCG 30 |
| 55253007230 | FENTANYL CITRATE EQ ORAL TRANS 600MCG 30 |
| 55253007330 | FENTANYL CITRATE EQ ORAL TRANS 800MCG 30 |

The registration is compliant for all of the SH locations associated with the Sold-to.

The Master Data Administrator (MDA) will access the **TIRF REMS Access Program** website <https://specialtyhealthreporting.mckesson.com/InfoViewApp/logon.jsp> every Monday of each week.

Enter the following information:

Username: teva\_mwoods  
Password: actavis0214 (all lower case)

NOTE: If you don’t use this website, after 90 days the account will be deactivated. After six months, it will lock you out of the website. You will need to click account setup. Account reset walks you through to set up.

You will have access to the following tabs in the **TIRF REMS Access Program**:

- **Distributor Enrolled** – participants that are enrolled in the TIRF REMS Access program
- **Distributor Incomplete** – ignore this tab, not applicable
- **Distributor Deactivated** – customers opt out of the program
- Click on **Corporate Categories>TIRF-REMS>Enrollment reports**. This will take you to the latest Distributor Reports and click on the Distributor Enrollment Detail, right click on document to **View Latest Instance or History**.
- To save the report to your computer, click **Document** dropdown button and click **Save report to my computer as>excel, choose either open or save**. You might get a pop-up screen that it is blocked, **click here for options** and **download** file to your computer.
- To print, click the print button be careful file is quite large.
- Click on **Document List**, this will take you back to the **Document Listing** or click **Home**.
- When you are finished using the website, click **log out**.



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| Page 7 of 12         |  |                 |              |

The participants that were enrolled in the Actiq/Fentora program will be grandfathered into the TIRF REMS ACCESS program, they will be enrolled under the “distributor section” under the enrolled tab.

If the participant party opts outs, or does not register to participate in the TIRF REMS Access Program, you can locate the data under “Distributor” **deactivated** tab.

When the customer’s registration is within 90 days of expiration, they will receive notice for renewal. Verify the new effective dates at the “distributor section” under the enrolled tab.

There are different scenarios for the REMS program but not limited to:

- If there is a new SP that is participating in the REMS program, you need to create a REMS registration from the valid date of the registration and the valid to is good for two years from that point that the registration was received.
- You need to verify that there is true SH’s at the Sold-to level that orders controls. Each SH must be a entity of the Corporate Office. For example, American Health Packaging and Testpak are repackagers and they shouldn’t be included in the REMS registration.
- If the Sold-to no longer participates in the TIRF REMS Access Program, you need to expire the REMS registration and add notes in the comment field that SP is no longer participating in TIRF REMS Access Program. There is no need to add exclusions since the REMS registration will be expired.
- If an order is placed for a participant that is no longer in the program, the order will go on license block. You can verify by SH location, that there was a REMS registration and the comment notes will show the reason for the expired registration.
- If there is an order that goes on license block, you will need to check the **Legal Control Issue Error Log Item** to view the reason for the block. It could block be either for DEA or State license and/or REMS registration. Look at the order and see what products are being ordered before going to the error log. If you notice it is Fentanyl products, than it is highly likely that it is due to a REMS registration issue.
- If the license block is for REMS, you need to search by SH location to see if there is a REMS registration and if there is, you need to check if the SH location was added to the registration.
- If the REMS registration is expired, you will need to contact the Customer Relations Administrator to handle.

NOTE: The external registration is “TIRFREMS” for all of the participating parties that have a REMS registration.

**7. Health Identification Number (HIN)**

If the HIN is being used, the Contracts Department need only submit the HIN. No additional documentation is required. The Master Data Administrator (MDA) will populate the current date in the “valid from” field and 12/31/9999 in the “valid to” field. On the ExpContrClass tab there is no need to include schedule numbers when creating a HIN, this field will be left blank. On the Customers tab, the MDA will need to add the customer account number and then accept the license under the Status tab. Input the SAP internal license number on the spreadsheet provided. Once all the HIN numbers have been created the updated spreadsheet needs to be forwarded to the Contracts Dept. if requested.

**8. License blocks**

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to license violations are investigated. Once the investigation has been completed the MDA will take the appropriate action necessary to either release the sales order hold or notify the appropriate Order Entry representative regarding the necessary action required in order to update the license. If customer contact is necessary to obtain a valid license, the MDA will make an attempt to contact the customer to obtain a valid license. If the MDA is unable to obtain a valid license after contacting the customer, the MDA will notify the CRA/SAA and the CRA/SAA will contact the customer to obtain a valid license. For example, if the order went to License Block (VE31) and the MDA noticed that the customer cannot receive 2 and 2N on their license, the MDA would notify the CRA responsible for that account (and Order Processing, if necessary) that the customer is not able to receive the product they ordered. This usually happens when it is an EDI order or sample order. Note: For IMA customers, when an order is on VE31 and IMA block; and the MDA goes into the order to release it they will see a pop up message that states the order is on IMA block, do not make ANY changes. The MDA should back out of the order immediately and do not save any changes. The MDA must wait until the order is released from the IMA block before releasing the order from VE31 License Block; otherwise this will cause an error with the order. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Actavis in order to streamline their inventory.)

**9. CII Schedule Drugs and SOMS blocks**

**SOMS – Suspicious Order Monitoring System (Of Control Drugs Substances)**

The Master Data Administrator (MDA) will be responsible to ensure that pending sales orders on hold due to suspicious order violations (SOMS) are investigated. The MDA will execute VA05 to determine the value and priority of the orders blocked due to SOMS violations. A MDA will print the SOMS form in a PDF file. The SOMS form contains Class of Trade (COT) averages and customer allowable/order and customer allowable/month. NOTE: A SOMS form **should not** be re- printed in the next month for a SOMS form printed from a previous month. Column values only show the current month and will no longer show the previous month’s values when printed later and will not be accurate to properly evaluation an order.

The MDA will review the SOMS form to determine if customer contact is necessary. If customer contact is necessary, the MDA will contact the customer. If necessary, the customer contact information can be obtained from the CRA responsible for the account. The MDA will contact the customer to determine if the order should be considered an ‘order of interest’. If the customer decides to cancel or reduce the quantity, they will need to provide a reason for the reduction or cancellation. All orders that require additional analysis should be communicated to the appropriate CRA and CRA Manager.





Actavis Pharma Inc.

**US Order Management**  
**Master Data / License Admin. Operational Procedure**



|                      |  |                 |              |
|----------------------|--|-----------------|--------------|
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| USOM POLICY #:       | USOM-LIC-4000  | Effective Date: | May 5, 2004  |
| Revision Written By: | Victoria Lepore<br>Mary Moskello   | Revision Date:  | June 5, 2014 |
| Page 8 of 12         |  |                 |              |

The following procedure is used to identify if the order is at or over the allowance Actavis gives the customer which will assist in determining the degree of analysis needed to release the order. Each order is evaluated and the best release code is applied to each order at that time.

Put the number that’s in the “Order Quantity” column into the “Release Qty” column. Then, mathematically ADD the following columns “MTD Qty” plus the “Release Qty” to give you a total order quantity to date.

- The ‘Pending Qty’ column on the SOMS form shows other orders (not the one currently being viewed) that are on SOMS block for the same customer and product. This is to make the MDA aware of other order quantities in the system. The MDA should take the ‘Pending Qty’ into consideration when completing the analysis of the current order (the one being viewed).
- When releasing the order the MDA will use the most appropriate reason code for each order.
- If the “MTD Qty” plus the” Release Qty” is equal to or less than the “Customer allow/mth”, then customer contact is not required.
- If the “MTD Qty” plus the “Release Qty” is greater than the “Customer Allow/mth”, then further analysis is need and SOMS form will need 2<sup>nd</sup> signature from management.

Some of the tools used during analysis:

- Current month call log.
- 852 & 867 data if available.
- Past shipping history; Year over Year (YOY) or Year to Date (YTD) comparison.
- Contact internal departments (i.e. Marketing, Demand Management, and CRA) to verify if they had information to assist in the analysis (i.e. Updated forecast, special orders, short-date, etc...).
- Customer contact.
- Controlled Substance Report – To update the report every day, open the current Controlled Substance Report and click **Start>All Programs>Business Explorer>Business Explorer (SAP BW 3)>Analyzer (SAP BW 3)**. At the top of the ribbon click **Add-Ins** and click the refresh button . You will get a pop-up screen to SAP Logon. Double click on SAP BW Production. You will get a pop-up screen to put your password. Make sure that Client – 300, User – your name, Password – enter password, Language, EN. Enter your password and press ok. You will get another screen called ZMKT\_M01\_Q0103: Trans. Click the execute button . The report will be updated and you will see the Last Refreshed date which will be today’s date. Save excel file to V:\Sales Operations & Distribution\Customer Master\Licensing Department\SOMS Calls\Controls Sales History.
- **Adding a new month to the Controlled Substance Report** – This is only done at the beginning of the month. First you need to **refresh query** and **execute** the report You need to go to **Cal/Year/Month field name**, do **right click on the field name** and go to **Select Filter Value**. You will get a pop-up screen called **Selection for Cal/Year/Month**. You need to take off the previous month (November 2012) and click the left blue arrow to move it to the left column called **Fixed Values** and then add the new current month (December 2012 or 12/2012), Click the right blue arrow to move it to the right column called **Selection** and **press ok**. The BW report will re-execute again showing the new month. **Adding new Material numbers for controls** – First you need to **refresh query** and **execute** the report. Right click on the **Material Number** field name and go to **Select Filter Values**. You will get a pop-up screen called **Selection for Material**. You need to add the new material number and/or NDC # for control substance only at the bottom on the **Fixed Values** column. Enter the new material number and click the right blue arrow to move it to the right column called **Selection** and **press ok**. At the end of the BW report, make sure the formula is copied several row for the new material numbers that were added.
- When contacting the customer via email, the following verbiage should be used.
- Subject: *“Company Name” Order(s) on Hold*
- Body of email:
  - *Hi (Addressee(s)), in accordance with 21 CFR 1301.74, we are required to conduct independent analysis of orders prior to completing a sale to determine whether substances are likely to be diverted from legitimate channels. You have been contacted due to the fact that your order placed today has prompted further analysis based on a deviation in one of the following areas; unusual size, frequency, or pattern. In an effort to expedite the investigation process and mitigate any delays or inconvenience, we are requesting supporting information necessary to justify the fulfillment of the order in question.*
  - *PO#*
  - *NDC#, Mat#, QTY*
  - *Please note the entire order is on hold. Your quick response will ensure your entire order will be released in a timely manner.*

*Salutation*

- The ‘Release Qty’ column on the SOMS form will need to be filled in by the MDA; this is the quantity that the MDA releases. Usually the ‘Release Qty’ is the same as the ‘Order Qty’, unless the customer requests to cancel the order or the MDA cancels the order with Management approval because the customer did not respond to the email sent by Master Data. ..
- If the customer decides to cancel the order, the MDA will request a reason for the cancellation of the order. Also, depending on the cancellation reason the MDA may forward the cancellation request to DEA Affairs for review. Please note: For IMA customers, if an increase is requested by the customer, the customer would need to be referred to the customer’s CRA to have that request completed, and the increased order quantity will go through IMA again. (IMA stands for Inventory Management Agreement, IMA customers are customers that have agreed to share confidential sales activity with Actavis in order to streamline their inventory.)
- If the customer is contacted, the MDA will attach supporting documentation to the SOMS form which will include the customer contact name, phone number and/or email, reason for the increase, PO#, SD#, and date of order, and the SKU/Material number and description of the product released. If the same SKU/Material suspends again in the same month, the MDA will determine if the original resolution is appropriate for subsequent orders or if further analysis is needed.



Actavis Pharma Inc.

**US Order Management**  
**Master Data / License Admin. Operational Procedure**

|                      |  |                 |              |
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| Revision Written By: | Victoria Lepore<br>Mary Moskello   | Revision Date:  | June 5, 2014 |
| Page 9 of 12         |  |                 |              |

- If the customer decides to cancel the order, then the order may come off of SOMS violation. The MDA will need to execute the VA05 again to verify the order is not on the VA05 list.
- The MDA group should make an effort to get to know the customers and their customers. With that said, if the customer’s response is a general response, i.e. increase due to new customers; it is recommended the MDA try to obtain the name, city, & state in which the new customer is located. Please know, the customer has the right to deny this request.
- The MDA will release and sign any orders that are 50 or less. These type of requests does not need management signature.
- The MDA will release and sign any order that is 50 or less on product launches or first time buys. These type of requests does not need management signature.

Once this SOMS form is confirmed and verified, the MDA will release the SOMS violation block. Otherwise, the MDA will escalate the ‘order of interest’ (SOMS) to the DEA Affairs department for review and feedback. If DEA Affairs determines the ‘order of interest’ (SOMS) needs to be communicated to the DEA. Then DEA Affairs will contact the DEA.

**B. Filing: Record Retention:**

- Class 2 and 2N’s are filed in a separate filing cabinet. The DEA requires all Class 2 and 2N’s to be filed separately from the 3, 3N, 4 and 5. All SOMS are filed by the account name, account number, City and State, by most current date. If within the same day there are multiple SOMS, then the most current Sales Document number is filed on top.

Also, there are four states Kansas, Kentucky, New York and Rhode Island which DO NOT allow CONTROLLED samples sent to ANY practitioners.

NOTE: If the customer requests to cancel the order or reduce a line quantity of a Class II (CII) order, an email of the change must be sent to Dept. Coordinator II in Gurnee.

**C. License for One Time Customer:**

The Master Data group will create a one-time Master Data template (shell) only once, as necessary. This shell will be used to create orders for one-time customers. A one-time customer shell will be used by order processing to create orders for situations where a permanent Master Data record is not needed, such as Tradeshow or Replacement Orders. **A One-time customer shell SHOULD NEVER be used for any site order or control substance order. A Customer Master account must be set up in order to place these order types.** These templates do not include entry of financial (company-level) data; as such, its usage should be restricted to free of charge orders (i.e., samples, literature etc.). If the one-time customer shell is used to generate a sales order, this record will supply basic customer master information and requires the order processing user to input key fields (i.e., name, address etc). The Master Data group will create the appropriate license for a one-time customer and link the license to the one-time ship-to customer’s sales order.

**D. Unlicensed Locations:**

If a representative receives an order for prescription drugs for an unlicensed location, he/she must obtain the license of an individual who will accept responsibility for drugs being shipped to that specific location.

Such customers may include:

- Dialysis Centers
- Universities
- Health Organizations
- Clinics
- Humanitarian Aid
- Family Planning/Planned Parenthood

The account will then have the Facility’s name in name 1 and the responsible doctor’s name in name 2, the facility’s address. The responsible doctor’s state license will be attached at the account level.

In the event the request is submitted with a Mid-Level Practitioner’s license, the Master Data Administrator (MDA) will verify that the Mid-Level practitioner is able to receive product by verifying their license on MedPro or checking with the manager of sample accountability. The Mid-Level Practioner’s name will then be on name 2 of the account.

On occasion an order will come in for an unlicensed Actavis facility. When the order comes in it will go to License Block (VE31). In order to release this order from license block, a mock license will need to be created; the license will only be valid for one business day. Once the order has shipped the license will be expired. Only a State License with a the single schedule of RX (no controls) will be created, the license number will typically be the first six characters of the city of the unlicensed facility or enough characters to be able to distinguish the location. For example if the order was going to Parsippany, NJ the license number would be PARSIP. The license will be attached at the account/Master Data level. If the order is for a TRADESHOW a mock license will be created as stated above except the license number will be “TRADESHOW”.

On occasion we will receive an order from the FDA for Samples which the FDA does not have a State Board of Pharmacy license. If this is the case, you will need to create a 1 day State license with the external license number with the word FDA followed by the 10 digit telephone number (i.e. “FDA3123535863”). Expire the license once the DD# has been created.

**E. Methamphetamine Control Act:**

The Master Data Administrator (MDA) will create a valid DEA or State license for any Meth Act products. The DEA license is preferred; if DEA is not available the State license will be used. The system will display the DEA or State license on the packing slip for all Actavis products; this is done to be in compliance with State regulations.



Actavis Pharma Inc.

**US Order Management**  
**Master Data / License Admin. Operational Procedure**

|                      |  |                 |              |
|----------------------|--|-----------------|--------------|
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| USOM POLICY #:       | USOM-LIC-4000  | Effective Date: | May 5, 2004  |
| Revision Written By: | Victoria Lepore<br>Mary Moskello   | Revision Date:  | June 5, 2014 |
| Page 10 of 12        |  |                 |              |

**F. Indigent Accounts:**

Dailies

These customers place orders on a daily basis and the account should be created in the physician’s name, even if his office is located in a hospital or clinic. If the physician wants to ship goods to numerous locations, a Sold-To should be created for the primary location and Ship-To’s should be created for the additional locations. All accounts are to be linked to the same state license even if the address does not match the license as long as this does not violate PDMA regulations. Note: The Sold-To address is usually the address that is on the physician’s state license, but the physician may choose not to ship goods to the address listed on the state license, in this case the physician will choose another address as the Sold-To. If, at a later time, the physician wants to ship goods to the address listed on the state license, that account may be created as a Ship-To and linked to the existing Sold-To.

Trelstar and Indigents


Trelstar and Indigent orders are top priority and should be released as soon as possible following standard procedures.

**G. PapSure Physician Address Changes:**


**NOTE: You do not need a license for PapSure orders, since the Material master record considers PapSure as an OTC product, therefore, the order should not be held up for a license.**

**H. R&D Research and Development:**

This section may pertain to Clinical Research, Calibration and Marketing Demonstration Requests. In-house shipments for prescription items to facilities for research and/or development purposes do not require licensing. Please refer to “Unlicensed Locations” section for in-house shipments. Shipments going to outside companies require a valid State or DEA license. **Exhibit A - NTIS National Technical Information Services**



Global Internet Management



NTIS  
National Technical Information Service  
U.S. Department of Commerce  
Data Source Data Selector Data Extractor

[HOME](#) | [DEA SEARCH](#) | [ONLINE REGISTRATION](#) | [CSA DATABASE](#) | [LISTING DATABASE](#) | [DEA API](#) | [ABOUT US](#) | [Login](#)

**SUBSCRIBER LOGIN:**

→ USERNAME:

→ PASSWORD:

[Forgot your password?](#)

[LOGIN](#)

**Drug Enforcement Administration (DEA) Controlled Substances Act Database Subscription Products**

This is the official site to search these two important DEA databases.

**Controlled Substances Act (CSA) Registration Database**

The Latest update : March 11, 2004

The *Controlled Substances Act (CSA) Registration Database* consists of records of individuals registered under the Controlled Substances Act including registrants doing business under their individual name rather than a business name. These records are used to credential the CSA status of health practitioners as well as organizations.


**LATEST NEWS:**

NTIS and GIM.net  
Announce Re-Launch  
of [deanumber.com](#)

NTIS and Global Internet Management created [deanumber.com](#) as a service to quickly and easily confirm DEA Registration numbers. The site contains a fully searchable database of all persons and organizations certified to handle controlled substances under the Controlled Substances Act of 1970.

Now, [deanumber.com](#) has been redesigned and upgraded based on GIM.net's premiere Content Management Software.

**This is the Official DEA Authorized Database**



SECURE SITE  
CLICK TO VERIFY

**Drug Enforcement Administration (DEA) Controlled Substance Act Registration Information Online Search - As of March 11, 2004**

Enter Search Criteria:

List Type

DEA#

Business Activity Code

Business Sub Activity Code

Expiration Date

Company / Doctor Name

State

Zip



Actavis Pharma Inc.

US Order Management  
Master Data / License Admin. Operational Procedure



|                      |  |                 |              |
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Page 11 of 12

Exhibit A – NTIS continued...

| DEA Number                | Exp. Date  | Company Name                  | State | Zip   |
|---------------------------|------------|-------------------------------|-------|-------|
| <a href="#">AC0393734</a> | 8/31/2005  | CITY PHARMACY INC             | TN    | 37745 |
| <a href="#">AT7665637</a> | 11/30/2005 | SUSONG PHARMACY               | TN    | 37745 |
| <a href="#">BS0143850</a> | 2/28/2007  | STUMM, HARRY J MD             | TN    | 37745 |
| <a href="#">BP3389793</a> | 3/31/2007  | PATTERSON, MARK DAVID MD      | TN    | 37745 |
| <a href="#">MM0369365</a> | 1/31/2005  | MCMILLIAN, JEFFREY OD         | TN    | 37745 |
| <a href="#">MR0552081</a> | 4/30/2005  | ROBBINS, MELISSA A FNP        | TN    | 37745 |
| <a href="#">MM0467426</a> | 1/31/2006  | MORRISON, REBECCA A PNP       | TN    | 37745 |
| <a href="#">MP0551033</a> | 3/31/2006  | PACE, NANCY L NP              | TN    | 37745 |
| <a href="#">MC0649472</a> | 8/31/2006  | CARRINO, THOMAS PA            | TN    | 37745 |
| <a href="#">BW0300220</a> | 5/31/2004  | WALGREEN CO                   | TN    | 37745 |
| <a href="#">BT4966288</a> | 11/30/2004 | THE MEDICINE SHOPPE           | TN    | 37745 |
| <a href="#">AC0401202</a> | 12/31/2004 | REVCO DISCOUNT DRUG CTRS, INC | TN    | 37745 |
| <a href="#">AR8276405</a> | 12/31/2004 | REVCO DISCOUNT DRUG CTRS, INC | TN    | 37745 |
| <a href="#">BF8029589</a> | 9/30/2005  | FOOD CITY PHARMACY #606       | TN    | 37745 |
| <a href="#">BH2489032</a> | 10/31/2005 | HOWARD'S PHARMACY             | TN    | 37745 |
| <a href="#">BR3339618</a> | 6/30/2006  | RITE AID OF TENNESSEE INC     | TN    | 37745 |
| <a href="#">BGR618689</a> | 9/30/2006  | GREENE COUNTY DRUG STORE, LLC | TN    | 37745 |

Select the hyperlink that matches the DEA information you are searching for.



Current Date: 3/15/2004Data File Release Date: March 11, 2004

Drug Enforcement Administration (DEA) Datafiles -Both

Registrant Profile

for

|                         |  |
|-------------------------|--|
| CITY PHARMACY INC       |  |
| Address:                | 113 E CHURCH ST<br>GREENEVILLE, TN 37745 |
| State / Zip:            | TN 37745                                 |
| DEA Number:             | AC0393734                                |
| Business Activity Code: | A  |
| Drug Schedule:          | 22N 33N 4 5                              |
| Expiration Date:        | 8/31/2005                                |

Print

Close

| Standard Abbreviations |  |  |  |
|------------------------|--|--|--|
| CRA                    | Customer Relations Administrator                                 |  |  |
| DEA                    | Drug Enforcement Administration                                  |  |  |
| MDA                    | Master Data Administrator  |  |  |
| MTD                    | Month to Date  |  |  |
| NTIS                   | National Technical Information Service                           |  |  |
| PDMA                   | Prescription Dug Marketing Act                                   |  |  |
| SOMS                   | Suspicious Order Monitoring System (of Control Drugs Substances) |  |  |
| YOY                    | Year Over Year   |  |  |
| YTD                    | Year To Date   |  |  |
|                        |  |  |  |



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**Master Data / License Admin. Operational Procedure**

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| Page 12 of 12        |  |                 |              |